K020866

JUN 11 2002

510(k) Summary

Category	Comments
Sponsor:	TheraSense, Inc. 1360 South Loop Road Alameda, CA 94502
Correspondent:	Donna K. Templeman Manager, Regulatory Affairs 1360 South Loop Road Alameda, CA 94502
Contact Numbers:	Phone: (510) 239-2670 Fax: (510) 239-2799
Device Common Name	Blood Glucose Meter and Data Management Software
Device Proprietary Name	FreeStyle Tracker™ Diabetes Management System
Device Classification Name	Glucose Test System Blood Lancet
Device Classification	Glucose Test System per 21 CFR 862.1345, Class II Device
Predicate Device	TheraSense, Inc., FreeStyle Blood Glucose Monitoring System TheraSense, Inc., FreeStyle Connect Data Management System
Predicate Device Manufacturer(s)	TheraSense, Inc.
Predicate Device Reference(s)	K992684; K000582; K012014; K994433
Predicate Device Proprietary Name(s)	TheraSense, Inc., FreeStyle Blood Glucose Monitoring System TheraSense, Inc., FreeStyle Connect Data Management System
Predicate Device Classification Name(s)	Glucose Test System Data Management Software
Predicate Device Classification(s)	Glucose Test System per 21 CFR 862.1345, Class II Device Data Management Software, no classification exists as of the date of subject device filing.

Date Summary Was Prepared: March 15, 2002.

Description of the Device:

The FreeStyle Tracker Diabetes Management System combines and joins the technologies and capabilities of both the FreeStyle Blood Glucose Monitoring System (blood glucose measurement testing system) and the FreeStyle Connect Data Management System (data management accessory software). Through the use of a Personal Digital Assistant (PDA), the user is able to conveniently log glucose measurements directly to a log history on the PDA. The Tracker System eliminates the necessity for manual data logs and separate tools for calculating values, storing results and producing and maintaining critical medical records. The blood glucose meter and data management system components of the Tracker System can also be used independently as separate features.

The items that comprise the FreeStyle Tracker Diabetes Management System are as follows:

- FreeStyle Tracker Measurement Module
- Personal Digital Assistant (PDA)
- "Hot-sync" Cradle
- FreeStyle Tracker Data Management Software

Additionally, in order to perform a blood glucose test the Tracker System requires the following items. These items are the same as those needed for the current FreeStyle System:

- FreeStyle Test Strips
- FreeStyle Lancing Device
- FreeStyle Lancets
- FreeStyle Control Solution

To perform a blood glucose measurement, the user removes the cover of the Visor PDA expansion slot and inserts the Tracker Measurement Module into the Visor PDA Handspring slot. The user then inserts a test strip into the Measurement Module. The user acquires a blood sample (with the test strip in the meter) by touching the edge of

the test strip to the blood target area, filling the chamber on the strip by capillary action. The Tracker System sounds a tone (beeps) to let the user know that the sample chamber is full and the reaction has begun. The test is complete and the meter displays the glucose reading on the PDA display.

The Tracker Data Management Systems also gives the user the ability to conveniently access and maintain diabetes data through the Visor PDA and/or PC. The user can easily and conveniently track major factors that affects their diabetes health, for example:

- Blood glucose levels
- Insulin usage (via injection or pump)
- Food intake
- Exercise
- Oral medication usage
- State of health

The Tracker DMS will also allow the user to enter personal factors used to maintain their proper glucose level. The following items assist the user to track and modify their lifestyle as it affects their diabetes health:

- Target glucose range
- Usual insulin type
- Typical insulin dose
- Insulin adjustment guidelines (determined by his/her healthcare professional)
- Meal schedule and guidelines (determined by his/her healthcare professional)
- Typical exercise type, duration and intensity

Intended Use:

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical setting to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf, and hand.

Technological Characteristics:

The fundamental scientific technology of the FreeStyle System has not been modified to result in the Tracker Diabetes Management System. The Tracker Measurement Module contains the same technology as the FreeStyle Meter in that the Tracker Measurement Module measures the electrical output from the glucose in whole blood reacting with the FreeStyle Test Strip chemistry. The measurement is then converted into glucose concentrations and displayed to the user.

Summary of

Testing:

System and component testing was performed with the Tracker Diabetes Management System to ensure the new device is equivalent to the currently marketed devices (FreeStyle Blood Glucose Monitoring System and FreeStyle Connect Data Management Software). These tests consisted of system, hardware, software, mechanical, packaging, electrical safety (EMC, EMI, and ESD) and clinical (user's study and labeling comprehension) evaluations. The changes to the FreeStyle System have been verified and validated demonstrating that the resultant changes have not affected safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Donna K. Templeman
Manager, Regulatory Affairs
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

JUN 11 2002

Re: k020866
Device Name: FreeStyle Tracker™ Diabetes Management System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Templeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K020866

Device Name: **FreeStyle Tracker Diabetes Management System**

Indication for Use:

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(Division Sign-Off)
Division of Clinical Laboratory ...
510(k) Number K020866

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** ✓

(Per 21 CFR 801.109)

(Optional Format 1-2-96)